

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

APOTEX INC. and APOTEX CORP.,

Plaintiffs,

v.

SYMPLMED PHARMACEUTICALS, LLC and
LES LABORATOIRES SERVIER,

Defendants.

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) C.A. No. 17-cv-00276-CFC-MPT
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STIPULATION AND ORDER

The Court, upon the consent and request of Plaintiffs Apotex Inc. and Apotex Corp. (collectively, “Apotex”), Defendants Symplmed Pharmaceuticals, LLC (“Symplmed”) and Les Laboratoires Servier (“Servier”) (together, “Defendants”), and third party Adhera Therapeutics (“Adhera”) (collectively, “Symplmed/Servier/Adhera”), hereby acknowledges the following Stipulation and issues the following Order.

STIPULATION

1. Symplmed was, and Adhera now is, the holder of New Drug Application (“NDA”) No. 205003 for PRESTALIA[®] (perindopril arginine/amlodipine besylate) oral tablets (2.5mg/3.5mg; 5mg/7mg; and 10mg/14mg), for which U.S. Patent No. 6,696,481 (“the ’481 patent”) and U.S. Patent No. 7,846,961 (“the ’961 patent”) are listed in the U.S. Food & Drug Administration (“FDA”) publication “Approved Drug Products with Therapeutic Equivalence Evaluations” as covering the PRESTALIA[®] Products and/or their FDA-approved use.
2. Servier is the owner of the ’481 patent and the ’961 patent.
3. Apotex submitted Abbreviated New Drug Application (“ANDA”) No. 209749 to, and seeks approval from, FDA to market generic perindopril arginine/amlodipine besylate

oral tablet products (2.5mg/3.5mg; 5mg/7mg; and 10mg/14mg) (the “Apotex ANDA Product”) prior to the expiration of the ’481 patent and the ’961 patent.

4. Apotex ANDA No. 209749 included a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (“Paragraph IV Certification”) to the ’481 patent and the ’961 patent, and Apotex provided notice of its Paragraph IV Certification to Defendants as required by 21 U.S.C. § 355(j)(2)(B) *et seq.*

5. Defendants filed no action for patent infringement within the statutory 45-day period following their receipt of Apotex’s notice of its Paragraph IV Certification, and pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5), Apotex filed the action captioned *Apotex Inc. and Apotex Corp. v. Symplmed Pharms., LLC and Les Laboratories Servier*, No. 1:17-cv-00276-VAC-MPT (this “Action”), seeking a declaratory judgment that the ’481 and ’961 patents are invalid and/or will not be infringed by the manufacture, importation, offer for sale, sale, and/or use of the Apotex ANDA Product.

6. This Court has subject matter jurisdiction over this Action and personal jurisdiction over Apotex and Defendants for purposes of this Action. Venue is proper in this Court as to Apotex and Defendants for purposes of this Action.

7. The Parties have settled this Action pursuant to the terms set forth in a Confidential Settlement Agreement, pursuant to which Symplmed/Servier/Adhera grant to Apotex a non-exclusive license to manufacture, import, offer for sale, and sell the Apotex ANDA Product in the U.S. as of the date, and upon the terms, set forth in the Confidential License Agreement.

8. Pursuant to the Court’s entry of the below ORDER, Apotex now seeks to dismiss this Action with prejudice.

Dated: March 5, 2019

/s/ Dana K. Severance

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Respectfully submitted,

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*Attorneys for Plaintiffs Apotex Inc. and
Apotex Corp.*

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Apotex and Defendants, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has subject matter jurisdiction over this Action and personal jurisdiction over Apotex and Defendants for purposes of this Action. Venue is proper in this Court as to Apotex and Defendants for purposes of this Action.
2. The filing and maintenance of the Apotex ANDA with a Paragraph IV Certification to the '481 patent and the '961 patent constitutes a technical act of infringement of the '481 patent and the '961 patent under 35 U.S.C. § 271(e)(2)(A).
3. Pursuant to the Confidential Settlement Agreement of the parties, all claims set forth in Apotex's Complaint in this Action are hereby dismissed with prejudice.
4. The Clerk of the Court is directed to enter this Stipulation and Order forthwith.

SO ORDERED this _____ day of _____, 2019

UNITED STATES DISTRICT JUDGE